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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/850,123	05/07/2001	Ian Hunter	1118/175	1166
2101	7590	04/21/2004	EXAMINER	
BROMBERG & SUNSTEIN LLP 125 SUMMER STREET BOSTON, MA 02110-1618			SODERQUIST, ARLEN	
		ART UNIT	PAPER NUMBER	
			1743	

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

11/

Office Action Summary	Application No.	Applicant(s)	
	09/850,123	HUNTER ET AL.	
	Examiner	Art Unit	
	Arlen Soderquist	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 06 February 2004.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-22 and 24-28 is/are pending in the application.
 4a) Of the above claim(s) 8-16 and 24 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,7,17-22 and 25-28 is/are rejected.
 7) Claim(s) 2-6 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

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1. The disclosure is objected to because of the following informalities: the current status of all nonprovisional parent applications referenced should be included.

Appropriate correction is required.

2. Claims 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 17 it is not clear how a continuous column can be formed if as required by claim 18 there is a gap between the adjacent platens. The problem appears to be that the term column can have different meanings to include the previously claimed "channel" and a column of liquid. Thus it appears that column needs to be further defined. For examination purposes claim 17 will be treated as including a liquid connection (column) between two plates that are separated by a small gap.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by Davis. In the patent Davis teaches a sample support for optical observation having an array of through holes. The drawings show a specimen tray or holder (1) to be employed for optical observation or analysis, and in particular for use in infrared microspectroscopy. The holder (1) includes one or more openings (2) and each opening is provided with an internal ledge or shoulder (3) and a specimen support (4) is supported on each ledge. Each support is preferably a disc-like member having a pair of generally flat, parallel, opposed surfaces and one or more unobstructed holes (5) extend through the support between the opposed surfaces. Each support is formed of a generally rigid material which will not be attacked by water or acids. Metals, such as stainless steel or gold; or plastic materials such as nylon, polytetrafluoroethylene (Teflon), or Kevlar, can be used to produce the support 4. As shown in the drawings, holes (5) are generally circular in cross section, but it is contemplated that the holes can have other cross-sectional configurations. Davis teaches that holes (5) have a diameter greater than 10 microns, generally in the range of about 10 μm and 13 mm. The cross sectional area or diameter of the holes is correlated with the

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surface tension of a liquid specimen to be analyzed, such that a film (6) of the liquid will span or enclose the holes, as shown in figure 2. This is taught as being adjustable to provide a quality spectrum based on the thickness of the sample being investigated. Holes (5) can all be of the same diameter or cross-sectional area, or alternately as illustrated in figure 2, the holes can have different diameters. With different diameter holes, the thickness of the liquid film which bridges or encloses the holes will vary with the hole diameter, and thus the operator can select a film thickness to provide the best quality spectrum. By directing an infrared beam through the unsupported film in one of the selected holes, an infrared spectrum of the specimen can be generated. In figure 2 the distance between the two holes is shown as less than the diameter of the holes.

5. Claims 17-18, 21-22, 25 and 27-28 are rejected under 35 U.S.C. 102(b) as being anticipated by de Macario. In the patent de Macario describes a carrier and a microsample holder (30) for use in horizontal beam spectrophotometers in place of conventional cuvette supports that normally are used with such spectrophotometers. The microsample holder is formed as a plate having a number of retaining elements preferably in the form of circular perforated areas for retaining drops of samples to be analyzed by the spectrophotometer. Columns 2-3 teach a sample holder of similar design is known for vertical beam spectrometers. Columns 7-8 teach that the holder (30) is formed with a set of retaining elements, such as a row of four retaining elements (32,34,36,38). The retaining elements are of circular shape with diameters on the order of about 3 mm, each retaining element being capable of retaining a 5-10 μ l sample of liquid to be analyzed. The surfaces of holder (30) other than the circular areas may be coated with a thin layer of hydrophobic material to assure retention of the liquid samples within the circular areas. The hole diameter permits the surface tension of the liquid sample to retain that sample stably within the confines of the hole. The remainder of holder (30) need not be light transmissive, it is, nevertheless, advantageous to its construction to construct the plate of transparent material, such as glass, plastic, quartz or the like. The holder (30) may be modified within the scope of the invention to have two or more rows of retaining elements, if desired, such as the rectangular pattern shown in figure 5 and described in column 7, lines 45-61 or column 11, lines 6-28. It is recognized that the holder is readily usable with the normal support-receptacle and automatic or manual indexing mechanism of conventional horizontal beam

spectrophotometers to pass through the center of each sample retained by retaining elements. In this respect the paragraph bridging columns 7-8 teaches that since the overall height, length and width of the carrier are identical (or substantially identical) to the height, length and width of the conventional cuvette support, the carrier is readily usable with the normal support-receptacle and automatic or manual indexing mechanism of conventional horizontal beam spectrophotometers. Thus, the retaining elements are aligned with the analyzing beam that normally passes through windows of the conventional cuvette support. It is seen that the analyzing beam thus passes through the center of each sample retained by retaining elements. The beam passes through only one sample at a time, and as the carrier is indexed, and successive samples are exposed to the beam. The patent also teaches that the de Macario device is meant to reduce the amount of sample required for the testing. The paragraph bridging columns 10-11 teaches the addition of reagents and samples to the holes of the device. Figure 8 and its associated discussion in column 10 teach the aligned placement of two identical plates separated by a relatively small distance. This small distance allows the liquid placed in one hole to form a liquid bridge between the aligned holes of two adjacent plates.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 19-20 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over de Macario as applied to claims 17-18, 21-22, 25 and 27-28 above, and further in view of Davis as

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explained above. De Macario does not teach the transfer of the fluid with any specific means or teach the claimed hole diameter. The Davis device includes a perforated member that is similar in structure to the de Macario plates that has a hole diameter including both the de Macario and instantly claimed diameters.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use smaller diameters within the range taught by Davis because of the ability to further reduce the sample volume and provide a quality spectrum using a single hole. Applicants are directed to the fact that the Courts have held the size of an article to be not a matter of invention; the discovery of an optimum value of a known result effective variable without producing any new or unexpected results is within the skill of the routineer in the art; and mere duplication of parts without any new and unexpected results is within the skill in the routineer in the art. See *In re Rose*, 105 USPQ 237 (CCPA 1955), *In re Boesch*, 205 USPQ 215 (CCPA 1980) and *In re Harza*, 124 USPQ 378 (CCPA 1960), respectively. Thus it would have been obvious to one of ordinary skill in the art at the time of the invention was made to optimize a density of holes and hole dimensions in order to produce a film thickness that would provide a proper spectra as taught by Davis and to provide a sufficient amount of sample to detect. It also would have been obvious to one of ordinary skill in the art at the time the invention was made to use notoriously well known devices for transferring fluids to the holes such as capillaries and cannula for their known ability of transferring small fluid volumes

8. Claims 1 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over de Macario as applied to claims 17-18, 21-22, 25 and 27-28 above, and further in view of Cole. De Macario does not teach the formation of a gradient of concentrations.

In the patent Cole teaches the production of a new antibacterially active agent. This new compound is designated clavulanic acid and in addition to being a broad spectrum antibiotic of medium potency, clavulanic acid and its salts and esters have the ability to enhance the effectiveness of β -lactam antibiotics against many β -lactamase producing bacteria. In example 42 Cole give an example of the antibiotic enhancement obtained for organisms when the two antibiotics are combined. The organisms were inoculated into Oxoid sensitivity test broth located in small wells in a plastic tray and containing separate concentration gradients of

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ampicillin, clavulanic acid sodium salt or ampicillin plus 1 µg/ml. clavulanic acid sodium salt (microtiter method). The tray was incubated at 37 °C overnight and a record made next morning of the end points of bacterial growth. The results reveal that the synergism markedly enhances the antibacterial activity of ampicillin against certain gram + ve and gram - ve bacteria.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the gradient concentrations of Cole into the methods of de Macario because of the ability to compare results for the different concentrations as shown by Cole.

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claim 26 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 8-9 of U.S. Patent No. 6,387,331 in view of de Macario as described above. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claim is of a scope that totally encompasses the patented claims except that the hole size range is different and the patented claims do not require different liquids in adjacent through holes. However there is a substantial overlap in the range and one cannot realistically make the patented device without also falling within the scope of claim 26. Additionally the intended use of the patented claims is either manipulating or analyzing distinct liquid samples (see the preamble of claims 1-2). Since d Macario shows a platen similar to the claimed platen used for analysis of distinct liquid samples, it would have been obvious to place distinct liquid samples into adjacent through holes as taught by de Macario to allow the analysis of a plurality of samples as taught by de Macario.

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11. Claims 2-6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The art does not teach or fairly suggest the methods as claimed in these claims.

12. Applicant's arguments filed February 6, 2004 have been fully considered but they are not persuasive. Relative to claims 1 and 7 examiner points out that both claims are of a scope that would include transferring a different volume of the second liquid to the containers as the contacting step. There is no requirement that the contacting be done simultaneously and so using a pipet or other well known transfer means to perform the contacting step is fully within the scope of these claims. Additionally, the claims are using open language which does not require the two steps to be performed in succession. Thus a step such as drying could also be inserted between the two liquids being introduced/contacted with the containers. In this way the pre-anchoring of reagents discussed by de Macario in column 10, line 55 to column 11, line 5 constitutes the first liquid introduction and the sample addition would constitute the second liquid contacting step. The Cole patent clearly teaches the formation of a gradient and reasons for the formation. Relative to claims 17-20, applicant is reading the cited passage of de Macario narrower than it was written. A proper reading of the passage is that the liquid sample is placed minimally on one of the retaining elements and the gap is such that a liquid bridge can form which would transfer fluid from one retaining element to the adjacent aligned retaining element. The liquid bridge of de Macario is the claimed column. The manner in which applicant was reading the de Macario section is directly applicable to the argument relating to claims 21-22 and 27-28 in that if the adjacent retaining elements (132,136) of figure 8 each contain a liquid, then the formation of the liquid bridge inherently allows the claimed mixing to occur. Relative to claim 25 and the diffusion of light, examiner would like to point out that the claim requires placing (entraining) a liquid into a plurality of adjacent parallel channels followed by illumination one side of the plurality of channels and allowing the light to come out the other side of the channels. There is no limitation placed on the liquid or the number of channels that are simultaneously illuminated by the light source in the claim. Thus it appears that simply passing light through the liquid in the channels creates the diffuse light as the light exits from the liquid filled channel(s). In this way passing light through the liquid filled holes/retaining

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elements or Davis or de Macario inherently meets the claim limitation. The section apparently referred to by applicant (page 35, lines 21-24), is not commensurate with the scope of claim 25 and therefore the argument is not persuasive. Relative to claim 26, applicant is directed the fact the de Macario reference clearly teaches placing different samples in the different openings and a coating of a hydrophobic material around the holes to assure retention of the liquid within the hole (column 7, lines 12-16). Thus these are not features that there is a need to be taught in the secondary references and the major difference between the device of de Macario and claim 26 is one of the size of the through-holes. Thus the question becomes what is the size available for through-holes intended to retain liquids for analysis and the capability of analytical instruments to perform the analysis. In this respect the Davis reference clearly teaches through-holes intended to retain liquid a scale that includes both the size taught by de Macario and that required by the instant claims. Applicants are directed to the fact that the Courts have held the size of an article to be not a matter of invention; the discovery of an optimum value of a known result effective variable without producing any new or unexpected results is within the skill of the routineer in the art; and mere duplication of parts without any new and unexpected results is within the skill in the routineer in the art. See *In re Rose*, 105 USPQ 237 (CCPA 1955), *In re Boesch*, 205 USPQ 215 (CCPA 1980) and *In re Harza*, 124 USPQ 378 (CCPA 1960), respectively. Relative to the obviousness-type double patenting rejection, examiner has added the de Macario reference into the rejection to show the obviousness of placing different liquids in adjacent holes to fulfill the intended purpose of the patented claims.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose current telephone number is (571) 272-1265 as a result of the examiner moving to the new USPTO location. The examiner's schedule is variable between the hours of about 5:30 AM to about 5:00 PM on Monday through Thursday and alternate Fridays.

A general phone number for the organization to which this application is assigned is (571) 272-1700. The fax phone number to file official papers for this application or proceeding is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



April 20, 2004

ARLEN SODERQUIST
PRIMARY EXAMINER